<u>What is claimed is</u>:

1. A method for analyzing a sample for binding events when a substance of interest is present with the sample, comprising:

establishing at least one of a setting and a position for an instrument that includes a control and that is involved with making determinations related to at least the presence of the substance of interest with the sample;

positioning the sample relative to a light source that outputs a light beam;

receiving said light beam by at least portions of the sample;

collecting scattered light from the sample portions using a light collection device of said instrument;

processing digital image data based on said light collected during said collecting step using said control of said instrument; and

counting objects after said processing step using digital information in determining at least whether the substance of interest is present with the sample.

2. A method, as claimed in Claim 1, wherein:

said establishing step includes providing magnification related to collecting said scattered light.

3. A method, as claimed in Claim 1, wherein:

said establishing step includes locating an optical subsystem in a direction relative to the sample.

4. A method, as claimed in Claim 1, wherein:

said establishing step includes locating said light source such that said light beam is at a desired angle relative to the sample.

5. A method, as claimed in Claim 1, wherein:

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said collection device includes a photoelectric device and said establishing step includes regulating at least one of integration time and gain related to said photoelectric device to provide desired light contrast.

6.   A method, as claimed in Claim 1, wherein:

said light beam includes a laser beam and the sample is associated with a test spot and said establishing step includes having said laser beam encompass at least all of said test spot with uniform light intensity.

7.   A method, as claimed in Claim 1, wherein:

said positioning step includes moving at least one of the sample and said light beam.

8.   A method, as claimed in Claim 1, wherein:

said processing step includes receiving electrical signals from said light collection device and obtaining said image data using said electrical signals.

9.   A method, as claimed in Claim 1, wherein:

said processing step includes using at least a first light intensity related procedure and at least a first size related procedure.

10.   A method, as claimed in Claim 9, wherein:

said first light intensity related procedure includes at least one of: enhancing a dynamic range related to light intensity; implementing at least one lookup table application related to light contrasting; performing a thresholding function related to light intensity; and utilizing a lower limit threshold based on pixel values associated with said light collection device.

11.   A method, as claimed in Claim 10, wherein:

said performing step includes using a histogram analysis.

12.   A method, as claimed in Claim 9, wherein:

said first size related procedure includes at least one of: conducting a morphology application; filtering using at least one parameter related to size; and performing a connectivity function related to adjacent objects.

13.   A method, as claimed in Claim 1, wherein:

said processing step includes providing a lower limit threshold based on histogram-related information.

14.   A method, as claimed in Claim 1, further including:

storing information in memory of said control related to said at least one of said setting and said position.

15.   A method, as claimed in Claim 1, further including:

adjusting at least one of integration time and gain associated with said light collection device after conducting at least some of said processing step.

16.   A method, as claimed in Claim 1, wherein:

the sample includes a test spot comprised of at least a first subspot and a second subspot immediately adjacent to said first subspot and in which said processing step includes obtaining said image data using said collection device from said first subspot, and separately obtaining said image data from said second subspot, and said counting step includes counting objects from said first subspot before obtaining said image data from said second subspot..

17.   A method, as claimed in Claim 1, wherein:

the substance of interest is a first substance of interest and said image data from said first subspot includes information related to the first substance of interest when present and said second subspot has a second sample, different from the first sample, to be used in

5 determining whether a second substance of interest, different from the first substance of interest, is present.

18.   A method, as claimed in Claim 1, wherein:

said digital image data is based on a two dimensional array of elements.

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19.   A method, as claimed in Claim 1, wherein:

the sample has a light-scattering label that includes at least one of: colloidal gold, selenium, silica particles, magnetic particles, metal particles, metal coated particles and polymer particles and in which said polymer particles are made of at least one of: latex,

15 polystyrene, polymethylacrylate and polycarbonate.

20.   An apparatus for counting binding events associated with a substance of interest when present with a sample, comprising:

a test subsystem that holds at least a first sample;

a light subsystem that outputs a light beam directed to the first sample;

5   an optical subsystem that receives scattered light from the first sample;

a light collection device in communication with said optical subsystem that collects scattered light; and

a control that processes digital image data related to the scattered light collected by said light collection device, said control using processed data to identify binding events in

10 determining whether the substance of interest is present with the first sample.

21.   An apparatus, as claimed in Claim 20, wherein:

said control conducts at least a first procedure related to light intensity and conducts at least a second procedure related to size to provide said processed data.

22.   An apparatus, as claimed in Claim 20, wherein:

said processed data includes first processed data obtained by said control executing software that enhances light contrast of said image data based on said light intensity.

23. An apparatus, as claimed in Claim 20, wherein:

said processed data includes second processed data obtained by said control executing software for use in obtaining a lower limit threshold related to said light intensity.

24. An apparatus, as claimed in Claim 20, wherein:

said processed data includes third processed data obtained by said control executing software that filters said image data based on information related to size.

25. An apparatus, as claimed in Claim 20, wherein:

said processed data includes fourth processed data that enhances differences related to said image data based on said light intensity.

26. An apparatus, as claimed in Claim 20, wherein:

said processed data includes a lower limit threshold that is obtained by said control executing software related to a histogram based on pixel values.

27. An apparatus, as claimed in Claim 20, wherein:

said processed data includes a plurality of magnitudes related to said light intensity that are at least equal to or greater than a lower limit threshold.

28. An apparatus, as claimed in Claim 20, wherein:

said light collection device includes a photoelectric device having a first setting related to integration time and a second setting related to gain.

29. An apparatus, as claimed in Claim 20, wherein:

said test subsystem is movable in a X direction and a Y direction using said control and a X-Y subsystem, the sample includes a plurality of test spots including a first test spot and a second test spot, said first test spot being defined to have at least a first subspot and a

5   second subspot and in which said control and said X-Y subsystem moves said test subsystem to enable said light beam to be directed to said second spot.

30.   An apparatus, as claimed in Claim 20, wherein:

said light beam is caused to move in a X direction and a Y direction using said

10   control.

31.   An apparatus, as claimed in Claim 20, wherein:

said control includes a memory for storing at least one of the following positions and settings associated with the apparatus: a magnification associated with said optical subsystem; a position of said optical subsystem in a Z direction, an angle related to said laser

5   subsystem; an integration time of said light collection device; and a gain of said light collection device.

32.   An apparatus, as claimed in Claim 20, wherein:

said control includes a display that displays histogram-related information.